CellPro, Inc.

(CPRO/FY ends Mar./$6 1/2)
Notes: a, e, f
Recommendation: **Strong Buy**

H&Q
HAMBRECHT & QUIST LLC
SPOT REPORT

BIOTECHNOLOGY

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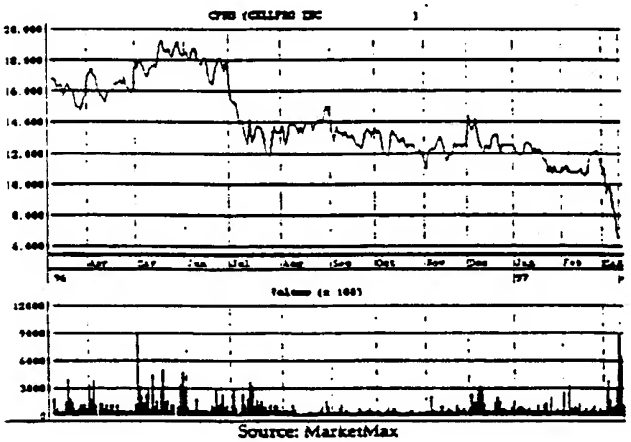
WILL THE PAIN EVER END? IT'S ALMOST OVER



Source: MarketMax

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Estimates	Q1	Q2	Q3	Q4	FY
'97 EPS					($1.52)
'97 Revenues					$13.7
'98 EPS					($0.35)
'98 Revenues					$41.8
Revenue Estimates in Millions					

Review of Events

CellPro has lost over 40% of its market value as the latest trial evolving from its patent dispute with Baxter/Becton Dickinson/Johns Hopkins has run its course, and investors are wondering when or more importantly if the slide will stop. Unfortunately, there is one more shoe to drop, which could come today, before this debacle concludes and CellPro can go on to appeal this case. A quick recap: On Tuesday afternoon the jury in the case awarded Baxter $2.3 million, the maximum it was asking for, and following the judges pre-deliberation directions, found for willfulness. Yesterday, in a press release Baxter announced that it would seek to enjoin sale of the Ceprate system in the US (the patents do not cover Europe or Asia). Today there is a hearing to discuss enhanced damages stemming from the ruling.

Yet Another Shoe to Drop?

Consistent with his actions throughout the case, we expect that the judge will rule in Baxter's favor and (1) treble the damages awarded by the jury, to a total of almost $7 million, (2) award Baxter its legal expenses, which could total about $15 million, but we would not be surprised if Baxter claimed they were higher, and (3) grant Baxter's request for an injunction. All of these issues will not be determined at the hearing, especially the issue of the injunction, which will probably take a few weeks to be imposed. With all that news still ahead, why would anyone still want to be an owner or buyer of CellPro? First and foremost for the reason that we continue to believe that this highly unusual and unprecedented decision will be overturned upon appeal and that CellPro will prevail. Second, at this point we believe that this potential bad news has been discounted as likely to occur and is reflected in the stock price, which is near our estimated valuation of its cash and ex-US business. After today's hearing and the eventual imposition of the three penalties listed above, CellPro will finally be free to move on to the appeals process, under new jurisdiction.

Will Penalties Overwhelm CellPro?

Concern has arisen that if the total damages awarded to Baxter by the judge exceed $20 million, and the product is enjoined from sale in the US, that CellPro will be unable to survive long enough to see the matter through the appeal. We believe that such concerns are unfounded. Whatever the eventual damages turn out to be, CellPro does not write a check for that amount. The standard practice is to purchase an appeal bond, which would cover the penalty until the appeal is resolved. If the judge issues an injunction, CellPro will receive expedited review (days to weeks) of its appeal of the injunction alone in a different court. We believe that an injunction would be rapidly overturned in the interest of the public health, and because it is a tough case to argue Baxter is being irreparably harmed since its competing system is not yet approved for sale in the US. If the injunction is overturned, the judge could order that CellPro pay, or set aside a royalty to Baxter that he determines reasonable. Regardless of what that rate is, we expect that CellPro will be free to continue selling the product in the US, and more importantly will have more than sufficient resources to see the dispute through appeal.

Baxter's Filing Not a Real Concern

Another area of concern is that Baxter's competitive cell separation system, Isolex 300, could be much closer to US approval than we had estimated. As we mentioned in an earlier report, during the trial Baxter surprised many (including us) when it stated that it had filed a PMA with the FDA seeking US approval. We continue to maintain our belief that this PMA is simply a strategic move to improve the appearance of its competitive position, and has little chance of approval. Baxter has been developing the Isolex 300 for about as long as CellPro has been developing Ceprate. Both received CE Mark authorization to sell the product in Europe in 1995. Even though Baxter received CE Mark six months ahead of CellPro, since that time CellPro has achieved over 80% estimated market share in Europe with a salesforce about 1/10th the size. In its recent press release, Baxter stated that over 800 patients have been treated with cells processed with the Isolex 300 system since its introduction, as compared to over 5,000 patients treated with Ceprate purified cells. Both these facts would confirm our view of CellPro's Ceprate as the superior product. The majority of patients for both companies has been in Europe in our opinion. To our knowledge, Baxter has not initiated a pivotal trial in the US. Based on precedent, we would expect such a trial to include 100-200 patients, be randomized with one arm of patients receiving Isolex-processed cells and one arm receiving unprocessed cells. We would expect this trial to take about one year to enroll, and the FDA requires one year follow up of all patients. With six months to compile and file the data and six months for FDA review results in three year total time from pivotal trial initiation to approval. There is a chance that Baxter has had such a trial underway below the market's (and our) radar screen for the past few years, but we view the likelihood of that as next to nil. Most likely in our opinion, Baxter's PMA consists of an non-randomized collection of European patients treated with cells from the Isolex 300 matched against historical controls. We could not foresee under any circumstances the FDA accepting such a PMA filing, much less approving it.

The Isolex 300 system that Baxter has filed for approval is actually the first generation product using its technology. In the fall of 1996, the company introduced its re-engineered Isolex 300i system, which we view as a significant improvement of the technology. In contrast to CellPro proprietary avidin-biotin system, Baxter utilizes a magnetic bead separation technology. Magnetic beads are very effective at selecting desired subpopulation of cells, and are especially well suited for negative selection, or purging certain cells. However, for positive selection, where the selected cells are intended to be given back to the patient, the magnetic beads

must be removed from desired cells prior to reinfusion, making it a much more complicated processing. With the first-generation Isolex 300 system, the magnetic beads are released from the desired cells with an enzyme called chymopapain, which quite simply digests all the proteins on the outside of the cells. While it is an effective technique to remove the magnetic beads, external proteins are important to cell growth and signaling. Baxter claims that these external proteins regenerate in a short period of time, but there is evidence that enzyme exposure damages the cells and inhibits their growth. Baxter itself provides further confirmation of the shortcomings of using enzyme release technique. In addition to significant engineering alterations the new Isolex 300i has eliminated the chymopapain and uses a proprietary peptide release technology that drops the beads off the cells without damaging the important extra-cellular proteins. Baxter researchers presented evidence at the American Society of Hematology (ASH) meeting in 1995 that cells from the new peptide release technology showed a significant increase in *in vitro* expansion as compared to chymopapain released cells. Since the peptide release system does not have any stimulatory activity on its own, these data appear to confirm the theory that chymopapain can be harmful to cells. The bottom line is that while the new Isolex 300i is a significant improvement in our view as compared to the older Isolex 300, the PMA submitted is from data using the first generation technology, which we believe has little chance of ever gaining approval.

Baxter's Strategy

Baxter has been widely reported to be attempting to sell the division developing the Isolex 300 and 300i systems. We feel it highly unlikely that a large third party (such as Amgen, Novartis, Rhone Poulenc Rorer, etc.) with a potential interest in Baxter's business and technology would be willing to purchase this business until this legal dispute with CellPro is resolved one way or another. A smaller buyer with lesser resources would be even less willing to take on the potential risk, in our view. As a result, we believe Baxter believes it imperative to resolve this dispute as soon as possible. If Baxter can bring enough pressure to bear on CellPro to force them to take a license to the patents, it would (1) further validate the patents' value and thereby Baxter's franchise, (2) remove the risk that the patents are ruled invalid on appeal, and (3) end this lawsuit, greatly improving the likelihood of a sale of its division. If, however, CellPro holds fast and pursues the matter in the appellate court, which we expect, then Baxter must support the division for about another year, which would include paying additional legal expenses. The stakes could be even higher for both parties. If CellPro prevails upon appeal and the original jury verdict is reinstated, which we believe to be likely, then CellPro can pursue the next leg of its lawsuit. CellPro has claimed that Baxter misused the patents in question in an attempt to extract European and Japanese marketing rights to the Ceprate system. If Baxter loses that case, the damages could be large in CellPro's. Even if CellPro had to put aside a $25 million penalty and was blocked from the US market, the $35 million in remaining cash could last them at least two years (longer if it cuts back on clinical development expenses), which would be more than enough time for the appeal court to rule on the case. When the current proceedings are concluded in the next few weeks, regardless of how onerous the outcome for CellPro, we do not believe Baxter will have enough leverage to force CellPro's hand to license the patents and end the dispute, and thereby Baxter will have to see the matter through appeal.

The Court Would Like to Thank the Jury for...

What is especially unusual about this case in our opinion is that the judge, not the juries, has determined the outcome. There are four critical issues in this (and many other) patent case: (1) the validity of the patents in question, (2) the infringement of the patents, (3) the willfulness of infringement, (4) and damages that should be awarded due to the infringement. In the original trial of the dispute between CellPro and Baxter a jury unanimously found regarding the first issue that the patents were invalid for reasons of lack of enablement and obviousness. On the second issue, the jury determined that CellPro did not infringe the patents anyway. Obviously this decision negated the need to deliberate the latter two issues. However, the judge chose not to enter this jury decision, but before sending it back to trial before another jury, he overruled the jury's decision, ruling first that the patents were valid and second that CellPro infringed these patents. Following these rulings, the judge stated that the jury's deliberations in the second trial (which concluded this week) would be limited to the issues of willfulness and damages. Even though we view the issues of validity and infringement to be the most important, the last two issues were also effectively determined by the judge. On the third issue as to whether the patents were willfully infringed, the judge instructed the jury prior to its deliberations, that "any reasonable jury" would find for willfulness, which in our view predetermined the outcome of that decision. On the final issue of damages, the jury awarded $2.3 million, the maximum in their power but not of significance to CellPro, which has about $60 million in cash. However, the judge has the authority to treble these damages, and due to the finding of willfulness, can award Baxter legal fees which could amount to $15 million or more, which

could bring the total near $25 million, which is greater than CellPro has received in total revenues from international Ceprate sales over the past three years. Effectively, the judge can impose a penalty on CellPro that will be 10X what the jury awarded, which could have a dramatic impact on CellPro's future. Finally, this same judge can grant Baxter's motion for injunction, removing the Ceprate system from the US markets. As we stated above, we believe it likely that the judge takes all these measures. If these events transpire as it appears they will, it begs the question as to why two juries were involved in this dispute at all.

Summary

Eventually, this patent case will be resolved, and we believe that the worst case scenario will involve CellPro paying a modest up-front fee and a modest royalty to Baxter along the lines of the previous licenses that were issued. We still believe that its more likely that CellPro will pay nothing and be free to sell the Ceprate system worldwide. **The critical investment concern regarding CellPro, in our view, is what is the eventual size of the Ceprate business, and this question will not be answered definitively until the second half of 1997, when additional sales and clinical data will be released.**

Company Overview

CellPro has several products and product candidates in therapeutic, diagnostic, and research applications based on its proprietary cell separation technology, called CEPRATE. The lead therapeutic product of the company is the CEPRATE SC system, a unique system that can be used to separate a small number of specific cells from complex cell mixtures for use as a transplant to rescue patients from infections and bleeding in high dose cancer chemotherapy (HDCT). These cells are the early-stage cells in blood that divide and change many times to replace all cells in the blood, red, white and platelets as they mature and die. The CEPRATE SC is designed to purify the small fraction (<1%) of these cells from the a patient's 200-500 ml "buffy coat," the white blood cell mixture collected from either the bone marrow or peripheral (circulating) blood. The resulting small (5 ml) CD34+ enriched cell suspension contains all the cells necessary for a successful transplant, and greatly reduces the toxicity, storage and malignant cell problems caused by unpurified buffy coat progenitor cell transplants (PCTs), which are the current standard of care. We believe that CellPro's device provides a crucial incremental benefit to the existing transplant market and that will eventually allow a new, more broadly applicable market to emerge of therapy for cancer to become more accepted and more widely used. That new therapy is high dose chemotherapy (HDCT) enabled by peripheral blood progenitor cell (PBPC) support.

Notes

Additional companies mentioned in this report:

Symbol	Name	Notes
Amgen	AMGN	f
Baxter	BAX	f
Becton Dickinson	BDX	f
Rhone Poulenc Rorer	RPR	f

a) Hambrecht & Quist LLC maintains a market in these stocks.
e) The analysts covering these stocks have investment position.
f) Options are available on these issues.